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PTO/SB/08A (08-00)

<p>Substitute for form 1449, PTO, 3/1/90.</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(use as many sheets as necessary)</i></p>		<p><i>Complete if Known</i></p>	
Sheet	1	of	3
		<p>Application Number 09/528,682</p> <p>Filing Date March 20, 2000</p> <p>First Named Inventor PIZZA et al.</p> <p>Group Art Unit 1631</p> <p>Examiner Name M. Borin</p>	
		<p>Attorney Docket Number PP000342.0105</p>	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

Complete if Known

Application Number	09/528,682
Filing Date	March 20, 2000
First Named Inventor	PIZZA et al.
Group Art Unit	1631
Examiner Name	M. Barin
Attorney Docket Number	PP000342.0105

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner
Signature

Date Considered

11/09/05

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Unique citation designation number:

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* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

1.1.1 Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number.
1.1.2 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

6 Applicant is to place a check mark here if English language Translation is attached

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				Group Art Unit	1631
				Examiner Name	M. Borin
Sheet	2	of	3	Attorney Docket Number	PP00342.0105 (2300-0342.10)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
<i>Mir</i>	C1	Burnette, "The Advent of Recombinant Pertussis Vaccines." <i>Biotechnol.</i> 8:1002-1005 (1990)			
	C2	Burnette, <i>Vaccine Research & Development</i> Chapter 6, Marcel Dekker Inc., New York, New York (1992)			
	C3	Communication to EPO Concerning Replacement Claims for Filing with the EPO in Application No. 99922284.7 (2003)			
	C4	de Haan, et al., "Mutational Analysis of the Role of ADP-Ribosylation Activity in the Adjuvant Properties of the Escherichia Coli Heat-Labile Enterotoxin Towards Intranasally Administered Keyhole Limpet Hemocyanin." <i>Eur. J. Immunol.</i> 28:1243-1250 (1998)			
	C5	Del Guidice, et al., "Genetically Derived Toxoids for use as Vaccines and Adjuvants." <i>Vaccine</i> 17:S44-S52 (1999)			
	C6	Dickinson & Clements, "Dissociation of Escherichia coli heat-labile enterotoxin adjuvanticity from ADP-ribosyltransferase activity", <i>Infect. Immun.</i> 63:1617-1623 (1995)			
	C7	EPO Communication pursuant to Article 96(2) EPC relating to Application EP No. 94928455.8-2116 (2001)			
	C8	"Multicomponent Vaccine Development." <i>NIH Guide</i> Volume 22, Number 28 (1993)			
	C9	Green, Bruce, Curriculum Vitae			
	C10	Grant et al., "Role of trypsin-like cleavage at arginine 192 in the enzymatic and cytotoxic activities of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> 62:4270-4278 (1994).			
	C11	Hagen, Michael, Curriculum Vitae			
	C12	Hagiwara, et al., Effectiveness and Safety of Mutant Escherichia Coli Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine." <i>Vaccine</i> 19:2071-2079 (2001)			
	C13	Hartman, et al., "Native and Mutant Forms of Cholera Toxin and Heat-Labile Enterotoxin Effectively Enhance Protective Efficacy of Live Attenuated and Heat-Killed Shigella Vaccines." <i>Infect. Immun.</i> 67:5841-5847 (1999)			
	C14	Hazama, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by using a Recombinant Glycoprotein D Fused with Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2." <i>Immunology</i> 78:643-649 (1993)			
	C15	Hirst, et al., "Cholera Toxin and Related Enterotoxins as Potent Immune Modulators." <i>J. Appl. Microb. Symp. Suppl.</i> 48:26S-34S (1998)			
	C16	Hirst, <i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , Chapter 6, Academic Press, pgs. 104-130, (1999)			
	C17	Lobet et al., "Effect of site-directed mutagenic alterations on ADP-ribosyltransferase activity of the A subunit of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> 59:2870-2879 (1991)			
	C18	Lycke, et al., "Strong Adjuvant Properties of Cholera Toxin on Gut Mucosal Immune Responses to Orally Presented Antigens." <i>Immunol.</i> 56:301-308 (1986)			
	C19	Lycke, et al., "The Mechanism of Cholera Toxin Adjuvanticity." <i>Res. Immunol.</i> 198:504-520 (1997)			
	C20	Martindale, <i>Royal Pharmaceutical Society of Britain</i> Pharmaceutical Press, London, England, pgs. 1277-1304(1993)			
	C21	Rappouli, et al., "Structure and Mucosal Adjuvanticity of Cholera and Escherichia Coli Heat-Labile Enterotoxins." <i>Immunol. Today</i> 20:493-500 (1999)			
	C22	Spangler, "Structure and Function of Cholera Toxin and The Related Escherichia Coli Heat-Labile Enterotoxin." <i>Microbiol. Rev.</i> 56:622-647 (1992)			
	C23	Streatfield, et al., "Intermolecular Interactions Between the A and B Subunits of Heat-Labile Enterotoxin from Escherichia Coli Promote Holotoxin Assembly and Stability In Vivo." <i>PNAS USA</i> 89:12140-12144 (1992)			
	C24	<i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , 2 nd Ed., Academic Press, pgs. 696-697			
<i>Mir</i>	C25	Tsuji, et al., "Relationship Between a Low Toxicity of the Mutant A Subunit of Enterotoxigenic Escherichia Coli Enterotoxin and its Strong Adjuvant Action." <i>Immunology</i> 90:176-182 (1997)			

Examiner Signature	<i>Mir</i>	Date Considered	11/09/05
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Sheet	3	of	3	Attorney Docket Number	PP000342. 0105 (2300-0342.10)
				Application Number 09/528,682 Filing Date March 20, 2000 First Named Inventor PIZZA et al. Group Art Unit 1631 Examiner Name M. Borin	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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